

Notice of Allowability

Application No.

10/527,062

Examiner

Rei-tsang Shiao, Ph.D.

Applicant(s)

FURUISHI ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on 07/25/2007.
2. ☒ The allowed claim(s) is/are 1-7, 11 and 19-22, now are 1-12.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

1. This application claims benefit of the foreign application:

JAPAN 2002-265276 with a filing date 09/11/2002.

2. Amendment of claim 11, cancellation of claims 8-10 and 12-17 and addition of claims 18-22 in the amendment filed on July 25, 2007, is acknowledged. A declaration under 37 C.F.R. 1.132 filed on June 08, 2007 is also acknowledged. Claims 1-7, 11 and 18-22 are pending in the application. No new matter is found. Since the newly added claims 18-22 are commensurate with the scope of the invention, claims 1-7, 11 and 18-22 are prosecuted in the case.

Responses to Amendment/Arguments

3. Applicant's arguments regarding the rejection of claim 11 under 35 U.S.C. 112, first paragraph, filed on June 08, 2007 have been fully considered but they are not persuasive. The breadth of the claim is methods of use of the instant compounds effective to "treating pathological condition affected or induced by activation an ACE" without limitation (i.e., no named diseases). Furthermore, the instant claims cover "treating pathological condition affected or induced by activation an ACE " that are known to exist and those that may be discovered in the future, for which there is no enablement provided. The rejection of claim 11 under 35 U.S.C. 112, first paragraph is maintained. Since claims 10 and 12 have been cancelled, the rejection of claims 10 and 12 under 35 U.S.C. 112, first paragraph has been obviated. Since claims 8-10

have been cancelled, the rejection of claims 8-10 under 35 U.S.C. 112, second paragraph has been obviated.

4. Applicant's arguments regarding the rejection of claim 1-2 under 35 U.S.C. 103(a) over Tamas's HU 196834 in view of Green et al., filed on June 08, 2007, have been fully considered and they are persuasive. The side-by-side comparison between the instant compounds (i.e., R1 represents a hydroxyl-lower alkyl group) and comparative compounds in the applicant's declaration (dated 06/08/2007) has indicated that the instant compounds have a higher skin permeation rate. Since neither Tamas's (i.e., English-translated version) nor Green et al. discloses or teaches that the instant variable R¹ of formula (I) represents a hydroxyl-lower alkyl group, a lower alkoxy-lower alkyl group, or a lower alkoxy-lower alkoxy-lower alkyl group, the rejection of claims 1-2 under 35 U.S.C. 103(a) over Tamas's HU 196834 in view of Green et al. has been withdrawn herein.

EXAMINER'S AMENDMENT

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Thomas M. Cunningham on August 29, 2007. The application has been amended as follows:

In claim 11, lines 6, after "a cardiac disease", delete ", nephritis, and apoplexy"

In claim 11, line 6, after "a cardiac disease", insert

--selected from the group consisting of cardiac hypertrophy, cardiac failure, and myocardial infarct--

In claim 19, line 1, after "claim 11", delete "or 18"

Delete claim **18**.

Reasons for Allowance

6. The following is an examiner's statement of reasons for allowance:

Claims 1-7, 11 and 19-22 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to praline ester preparation containing the same for percutaneous administration. The closest reference is Tamas's HU 196834, which disclose process for the production of peptide derivatives containing a 1-carboxy-alkyl group N-terminally and acid addition salts. The difference between the reference and instant claims is that the instant compounds of formula (I) have not been found. A suggestion for modification of above reference to obtain the instant compounds/compositions and methods of use has not been found. Claims 1-7, 11 and 19-22 are allowed.

Any comments considered necessary by applicant must be submitted no later

than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Rei-tsang Shiao', with a stylized flourish at the end.

Rei-tsang Shiao, Ph.D.
Patent Examiner
Art Unit 1626

August 30, 2007